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09/307,511	05/07/1999	GUY BOURDON	PBLMD-51494	4934

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EXAMINER	
EREZO, DARWIN P	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/307,511	BOURDON, GUY	
	Examin r	Art Unit	
	Darwin P. Erezo	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 24-25 have been considered but are moot in view of the new ground(s) of rejection.

2. Applicant's arguments filed 10/7/02 have been fully considered but they are not persuasive. In response to applicant's arguments that the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, fails to teach the inspiration valve closed during expiration and the expiration valve being closed during inspiration, it should be noted the operating manual does teach the inspiration being stopped to allow for expiration, as shown in page 79, step 4. Furthermore, it would have been inherent to close the expiration valve to prevent the user from inhaling exhausted gases.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16, 20, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300.

5. **As to claim 16**, the Siemens Servo Ventilator 300 is a breathing aid device comprising:

a patient connection (it is inherent for the ventilator to have a connection to the patient;

an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3);

an expiratory branch in fluid communication with the patient connection and the inspiratory branch;

means for controlling expiration in fluid communication with the expiratory branch, the means for controlling expiration including an expiration valve (page 17, number 11);

means for detecting pressure operatively connected to the inspiratory branch (page 17, number 11); and

means for ventilating in fluid communication with inspiratory branch, the means for ventilating including means for supplying a breathable gas through the inspiratory branch at an adjustable pressure (pages 82-83), the means for ventilating further including means for controlling the inspiration valve and the expiration valve (page 17, number 11), wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration, the means for ventilating further including pressure control means for comparing a pressure command to a pressure signal provided by the means for detecting pressure and for adjusting the pressure of the means for supplying (page 83); and means for

regulating a patient's breathed volume, the means for regulating including means for controlling volume and means for measuring volume (page 83), wherein the means for controlling volume provides the pressure command to the pressure control means, and wherein the means for measuring volume provides a signal indicative of a measured volume of breathed gas to the means for controlling volume (page 84).

6. **As to claim 20**, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

7. **As to claim 21**, the Siemens Servo Ventilator 300 is a breathing aid device comprising:

a patient connection (it is inherent for the ventilator to have a connection to the patient;

an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3);

an expiratory branch in fluid communication with the patient connection and the inspiratory branch;

an expiration device in fluid communication with the expiratory branch, the expiratory branch including an expiration valve (page 17, number 11);;

a pressure detector operatively connected to the inspiratory branch (page 17, number 11);

a ventilation unit in fluid communication with the inspiratory branch, the ventilation unit including a source of breathable gas at an adjustable pressure (pages 82-83), the ventilation unit further including a valve controller for opening and closing the inspiration valve and the expiration valve (page 17, number 11), wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration, the ventilation unit further including a pressure controller for comparing a pressure detected by the pressure detector to a pressure command and for adjusting the pressure of the source of breathable gas (page 83); and

a regulator for regulating a patient's breathed volume, the regulator including a control unit and a measuring unit, wherein the control unit provides the pressure command to the ventilation unit , and wherein the measuring unit provides a signal indicative of a measured volume of breathed gas to the control unit (page 84).

8. **As to claim 23**, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a

minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, and in view of US 5,353,788 to Miles.

11. **As to claims 17 and 18**, the non-patent literature fails to specifically teach the patient connection comprising a facial mask or a nasal mask.

Miles teaches that it is known in the art to use a patient connection means comprising a nasal mask **26**, which is also facial mask.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a facial mask or a nasal mask since it is well known in the art to use a nasal mask or a facial mask to connect a patient to a ventilator.

12. Claims 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, and in view of US 4,941,469 to Adaham.

13. **As to claims 19 and 22**, the non-patent literature fails to teach an adjustable speed motor-turbine set.

Adaham teaches the use of an adjustable motor-turbine set in a ventilator.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adjustable motor-turbine set of Adaham in the Siemens Servo Ventilator in order to provide air flow to the ventilator.

14. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, and in view of US 5,647,351 to Weismann et al.

15. **As to claim 24**, the Siemens Servo Ventilator 300 is a breathing aid device comprising:

a patient connection (it is inherent for the ventilator to have a connection to the patient;

an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3);

an expiratory branch in fluid communication with the patient connection and the inspiratory branch;

an expiration device in fluid communication with the expiratory branch, the expiratory branch including an expiration valve (page 17, number 11);;

a pressure detector operatively connected to the inspiratory branch (page 17, number 11);

a source of breathable gas at an adjustable pressure in fluid communication with the inspiratory branch (page 17, number 3);

a valve controller for opening for opening and closing the inspiration valve and the expiration valve (page 17, number 11; it is inherent for the device to have a controller to control the valves);

a pressure controller for comparing a pressure detected by the pressure detector to a pressure command and for adjusting the pressure of the source of breathable gas (page 83);

a control unit for providing the pressure command to the pressure controller; and

a measuring unit for providing a signal to the control unit indicative of a measured volume of breathable gas detected per breathing cycle to the patient connection (page 84).

The non patent literature is silent with regards to the pressure detector disposed in the patient connection.

Wiesmann teaches a ventilatory support system having a pressure detector disposed in the patient connection.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to put the pressure detector on the patient connection because the location of the pressure detector is a mere design choice and that the device would work equally well with the pressure detector disposed inside the ventilator unit or the patient connection.

16. **As to claim 25**, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on (703) 308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Aaron J. Lewis
Primary Examiner

dpe
December 19, 2002